

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

CELGENE CORPORATION,

Plaintiff,

v.

HETERO LABS LIMITED, HETERO
LABS LIMITED UNIT-V, HETERO
DRUGS LIMITED, HETERO USA, INC.,
AUROBINDO PHARMA LIMITED,
AUROBINDO PHARMA USA, INC.,
AUROLIFE PHARMA LLC, EUGIA
PHARMA SPECIALTIES LIMITED,
APOTEX INC., APOTEX CORP., MYLAN
PHARMACEUTICALS, INC., MYLAN
INC., MYLAN, N.V., BRECKENRIDGE
PHARMACEUTICAL, INC., AND TEVA
PHARMACEUTICALS USA, INC.

Defendants.

C.A. No.: 17-cv-03387 (ES) (MAH)

CONSOLIDATED

**THE MYLAN DEFENDANTS' SUPPLEMENTAL OPENING CLAIM
CONSTRUCTION BRIEF**

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Pursuant to the Court’s Amended Scheduling Order (ECF No. 323), the Mylan Defendants respectfully submit the instant Supplemental Opening Claim Construction Brief.

I. INTRODUCTION

Three groups of patents are at issue in this case: (1) the ’262, ’939, and ’428 method of treatment patents (“the MOT patents”); (2) the ’427 and ’467 formulation patents; and (3) ’720, ’977, ’784, ’886, and ’531 patents, which are directed to a restricted distribution program—also known as a Risk Evaluation and Mitigation Strategy (“REMS”)¹ – for certain drugs (“REMS patents”).²

The Mylan Defendants respectfully submit that the additional term from the ’427 patent proposed for construction, “100% pure pomalidomide,” requires no construction because its meaning is readily apparent, and that the plain and ordinary meanings should apply. Both Celgene’s construction (“the free base of the active pharmaceutical ingredient pomalidomide, absent impurities, present in the final oral dosage form”) and Defendants Teva and Aurobindo’s construction (“the material 4-amino-2-(2,6-dioxopiperidine-3-yl)isoindoline-1,3-dione that is completely free of any other substance”) are repetitive, unnecessary, and will lead to further confusion and disputes between the parties.

II. LEGAL STANDARDS

“[T]he words of a claim are generally given their ordinary and customary meaning . . . to a person of ordinary skill in the art.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir.

¹ See 21 U.S.C. § 355-1, which authorizes FDA to require a REMS for certain drugs if FDA determines that a REMS is necessary to ensure that the benefits of the drug outweigh its risks. *In re Suboxone (Buprenorphine HCl and Naloxone) Antitrust Litig.*, 13-MD-2445, 2017 WL 36371, at *2 (E.D. Pa. Jan. 4, 2017).

² On January 22, 2019, the Court ordered the claims and defenses with respect to the REMS patent bifurcated and stayed (ECF No. 288).

2005) (en banc) (citation and internal quotations omitted). The claims “must be read in view of the specification, of which they are a part,” and the Court “should also consider the patent’s prosecution history.” *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979-80 (Fed. Cir. 1995) (en banc) (citations omitted), *aff’d*, 517 U.S. 370 (1996). Absent the limited circumstances of either lexicography or disavowal, that ordinary meaning controls. *GE Lighting Sols., LLC v. AgiLight, Inc.*, 750 F.3d 1304, 1309 (Fed. Cir. 2014). The Court is permitted to rely on extrinsic evidence, including expert testimony and learned treatises, to determine a claim term’s plain meaning, although extrinsic evidence is “less significant than the intrinsic record in determining ‘the legally operative meaning of claim language.’” *Phillips*, 415 F.3d at 1317 (citation omitted).

III. LEVEL OF ORDINARY SKILL IN THE ART

The person of ordinary skill in the art (“POSA”) to whom the ’427 and ’467 patents are directed is a person involved in the research and development of pharmaceutical formulations and dosage forms, and would have a Ph.D. in a field related to “pharmaceutical sciences” (such as pharmaceutics, physical chemistry, medicinal chemistry, chemistry, chemical engineering, or biochemistry) and at least one year of experience in pharmaceutical formulation.

The qualifications for the POSA can be met by one person or a team of individuals, and the skilled artisan could have a lower level of formal education if that person has a higher degree of experience.

IV. ARGUMENT

A. The ’427 Formulation Patent

Claims 3-10 of the ’427 patent are directed to oral dosage formulations in the form of a capsule, and each claimed capsule recites specific amounts of “100% pure pomalidomide,”

pregelatinized starch, and sodium stearyl fumarate, as well as a specific total weight of the composition.

1. “100% pure pomalidomide”

Claim Term	Celgene’s Proposal	The Mylan Defendants, Apotex, Breckenridge, and Hetero’s Proposal	Teva and Aurobindo’s Proposal
“100% pure pomalidomide” ECF No. 1, Compl. Ex. D, ’427 patent claims 3-10	“the free base of the active pharmaceutical ingredient pomalidomide, absent impurities, present in the final oral dosage form”	Requires no construction	“the material 4-amino-2-(2,6-dioxopiperidine-3-yl)isoindoline-1,3-dione that is completely free of any other substance”

The Mylan Defendants contend that “100% pure pomalidomide” need not be construed and that it should have its plain and ordinary meaning. Celgene’s and Teva and Aurobindo’s proposed constructions are both unnecessary and only add additional terms for construction. A finding that no construction is required, however, complies with the intrinsic evidence and how a POSA would understand this term.

First, the ordinary meaning of “100% pure pomalidomide” as that term is used within the context of the surrounding claim language is readily understood by a POSA. For example, subpart 1 of Claim 1 limits the amount of pomalidomide present in the claimed dosage form as follows: “pomalidomide, or a pharmaceutically acceptable salt or solvate thereof, at an amount that provides 0.5 mg of 100% pure pomalidomide.” Thus, a POSA would understand that the amount of pomalidomide that satisfies claim 1 is to be measured only by the amount of 100% pure pomalidomide present.

In addition, the individual terms within the phrase “100% pure pomalidomide” are also readily understood by a POSA. The term “100%” is self-explanatory and easily comprehensible by a POSA. The term “pure pomalidomide” is also readily understood by a POSA. For example, any impurities associated with the pomalidomide would be excluded from the weight calculation. Further, as previously explained in Defendants’ Opening Claim Construction Brief (ECF No. 250), a POSA would understand that, when a compound is in the form of a “pharmaceutically acceptable salt or solvate,” the presence of counter ions and solvent molecules increases the molecular weight over that of the compound alone. Thus, when the obtained form of pomalidomide is a salt, solvate, or otherwise less than 100% pure, the weight calculation of “100% pure pomalidomide” will exclude anything that is not the compound alone (e.g., counter ions, solvent molecules, impurities). Because a POSA would readily understand how to perform the weight calculation expressly described in the claims, no construction of “100% pure pomalidomide” is necessary.

In similar circumstances, Courts have often found that no construction is necessary when the ordinary meaning of a claim term is readily apparent to a POSA. *See, e.g., Supernus Pharm. Inc. v. Actavis Inc.*, No. 13-4740, 2016 WL 527838, at *5 (D.N.J. Feb. 5, 2016); *Schindler Elevator Corp. v. Otis Elevator Co.*, No. 09-cv-0560, 2010 WL 199600, at *6 (D.N.J. Jan. 13, 2010) (citation omitted) (finding no construction necessary where “the ordinary meaning of claim language as understood by a person of skill in the art [is] readily apparent” and therefore refusing to construe the term “all” because “[t]he meaning of the word ‘all’ is readily apparent to anyone reading the [patent]”); *Spectrum Pharm., Inc. v. Sandoz Inc.*, No. 2:12-cv-000111-GMN-NJK, 2013 U.S. Dist. LEXIS 181673, at *32 (D. Nev. Dec. 31, 2013) (finding “that a person of ordinary skill in the art of organic chemistry would understand the ’829 Patent to use these

‘percentage’ claim terms in accordance with their plain meaning. These phrases need no further construction.”).

Second, this understanding is supported by the specification of the ’427 patent. The ’427 patent’s claims include multiple, alternative forms for the active ingredient pomalidomide (i.e., “pomalidomide, or a pharmaceutically acceptable salt or solvate thereof”). The ’427 patent’s claims also explicitly identify the amount of pure pomalidomide to be found in the claimed capsule (i.e., “[x] mg of 100% pure pomalidomide”). ECF No. 1, Compl. Ex. D, ’427 patent claims. Thus, whatever the form of the pomalidomide is in the capsule (e.g., whether a salt, solvate, or free base), for purposes of determining whether the amount of pomalidomide meets that claim language, the weight of the pomalidomide is adjusted so as to provide only the amount of 100% pure pomalidomide present – e.g., excluding the salt or solvate weight. As stated in the specification:

In some embodiments, because it is typical to obtain pomalidomide, or a pharmaceutically acceptable stereoisomer, prodrug, salt, solvate, or clathrate thereof, at a purity of less than 100%, the formulations and dosage forms provided herein may be defined as compositions, formulations, or dosage forms that comprise pomalidomide, or a pharmaceutically acceptable stereoisomer, prodrug, salt, solvate, or clathrate thereof, at an amount that provides the potency of a specified amount of 100% pure pomalidomide.

ECF No. 1, Compl. Ex. D, ’427 patent at 7:26-34 (emphasis added); *see also id.* at Examples 1-6 (indicating weight for pomalidomide “corresponds to the amount that provides the potency of [x] mg of pomalidomide”).

Third, the prosecution history also supports the Mylan Defendants’ proposal of no construction required. The ordinary meaning of the term “100% pure pomalidomide” was explained by Celgene during prosecution of the ’427 patent. During the prosecution of the ’427 patent, the applicant changed the phrase “[x] mg potency of pomalidomide” to the current phrase “100% pure pomalidomide.” This was done to clarify that the phrase referred to the amount of

pomalidomide in the formulation. Ex. 1, '427 PH, June 17, 2013 Amendment and Resp. at CELPOM0001856. For example, the Applicants explained that more pomalidomide was necessary to reach a certain amount of pure pomalidomide:

[A]s those skilled in the art would clearly understand from this language, the claim contemplates that pomalidomide, or a pharmaceutically acceptable salt or solvate, would be contained in the claimed formulation in an amount that would provide the same potency as X mg of pomalidomide free base. In other words, the “mg” unit recited by the claims does not refer to the actual potency of the active ingredient, but instead **refers to the amount of pomalidomide free base that would provide the required potency.**

Ex. 2, '427 PH, Feb. 13, 2013 Amendment and Resp. at CELPOM00001823-24 (emphasis added). It is readily apparent what the term “100% pure pomalidomide” means based on the prosecution history, and thus, no construction is required for this term.

Fourth, the parties long ago submitted *Markman* briefing on any disputed claim terms in the '427 patent. During that round of briefing, no party sought to construe the term “100% pure pomalidomide.” By failing to identify it, every party acknowledged that the term “100% pure pomalidomide” was readily understood by a POSA and did not require construction. Celgene’s failure to timely identify this term for construction supports the Mylan Defendants’ argument that this term requires no construction and that it should have its plain and ordinary meaning.

Furthermore, Celgene’s and Teva and Aurobindo’s proposed constructions provide no clarity as their constructions are simply repetitive of the plain and ordinary meaning and add additional terms and confusion. For example, Celgene’s proposed construction adds additional phrases, such as “absent impurities” and “present in the final oral dosage form,” which do not appear in the claims or specification. Teva and Aurobindo’s proposed construction also presents a new phrase for construction, “completely free.” As Celgene previously noted, adopting constructions that add additional, undefined terms would only lead to a future dispute that would require additional effort from the Court to construe the meaning of these additional terms. For

this reason, both Celgene's and Teva and Aurobindo's proposed constructions should be denied.

See Depomed, Inc. v. Sun Pharma Glob. FZE, No. 11-3553, 2012 WL 3201962, at *5 (D.N.J. Aug. 3, 2012) (citation omitted) (rejecting "Defendants' proposed construction [that] would itself require additional defining," noting, that "the words the court uses in construing a claim should not be limitations that require additional interpretation.").

The term "100% pure pomalidomide" requires no construction and should have its plain and ordinary meaning. Neither Celgene nor Teva and Aurobindo thought this term required construction previously, and their proposed constructions now are simply repetitive of the readily apparent meaning. Adopting their proposed constructions would only lead to further disputes between the parties. For these reasons, the Court should find that no construction is required.

B. The '467 Formulation Patent

Claims 1-8 of the '467 patent are directed to oral dosage formulations in the form of a capsule, and each claimed capsule comprises pomalidomide and a binder or filler that is a mixture of starch and mannitol. Claims 6-8 of the '467 patent additionally contemplate adding a lubricant to the claimed capsule.

1. "pomalidomide"

Both Celgene and the Mylan Defendants, Apotex, Breckenridge, and Hetero agree that no construction is required for the term "pomalidomide." It is our understanding that Teva and Aurobindo are withdrawing the term for construction as well, therefore, no construction is required.

2. "lubricant"

The Mylan Defendants take no position regarding the construction of the term "lubricant."

V. CONCLUSION

The “100% pure pomalidomide” term does not require construction and should be given the plain and ordinary meaning. The Mylan Defendants believe that Celgene’s and Teva and Aurobindo’s proposed constructions provide no additional clarity to the meaning of the terms proposed for construction. Celgene and Teva and Aurobindo only add additional, new terms that have no intrinsic support and which would require additional construction by the Court. Because the meaning of this phrase is readily understood, and because the proposed constructions would require additional effort by the Court, the Mylan Defendants believe that no construction is required, and that the phrase “100% pure pomalidomide” should have its plain and ordinary meaning.

Dated: May 29, 2019

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